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(54) **APPARATUS AND METHODS FOR TRANSFERRING ULTRASONIC ENERGY TO A BODILY TISSUE**

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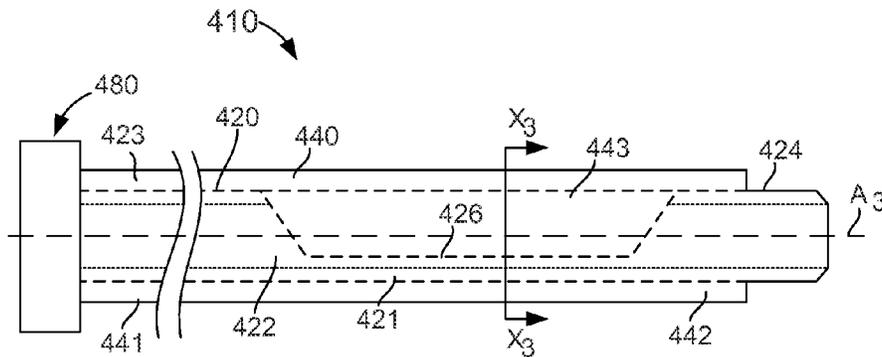
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(57) **ABSTRACT**

An apparatus includes a monolithically-constructed transmission member that defines a lumen along a longitudinal axis. The transmission member includes a first portion, a second portion, and a third portion. The first portion is configured to be coupled to an ultrasonic energy source. The second portion is configured to contact a bodily tissue to transfer ultrasonic energy from a first portion into the bodily tissue. The third portion is disposed between the first portion and the second portion and defines a cross-sectional moment of inertia that is less than at least one of a cross-sectional area moment of inertia of the first portion or a cross-sectional moment of inertia of the second portion.

16 Claims, 8 Drawing Sheets



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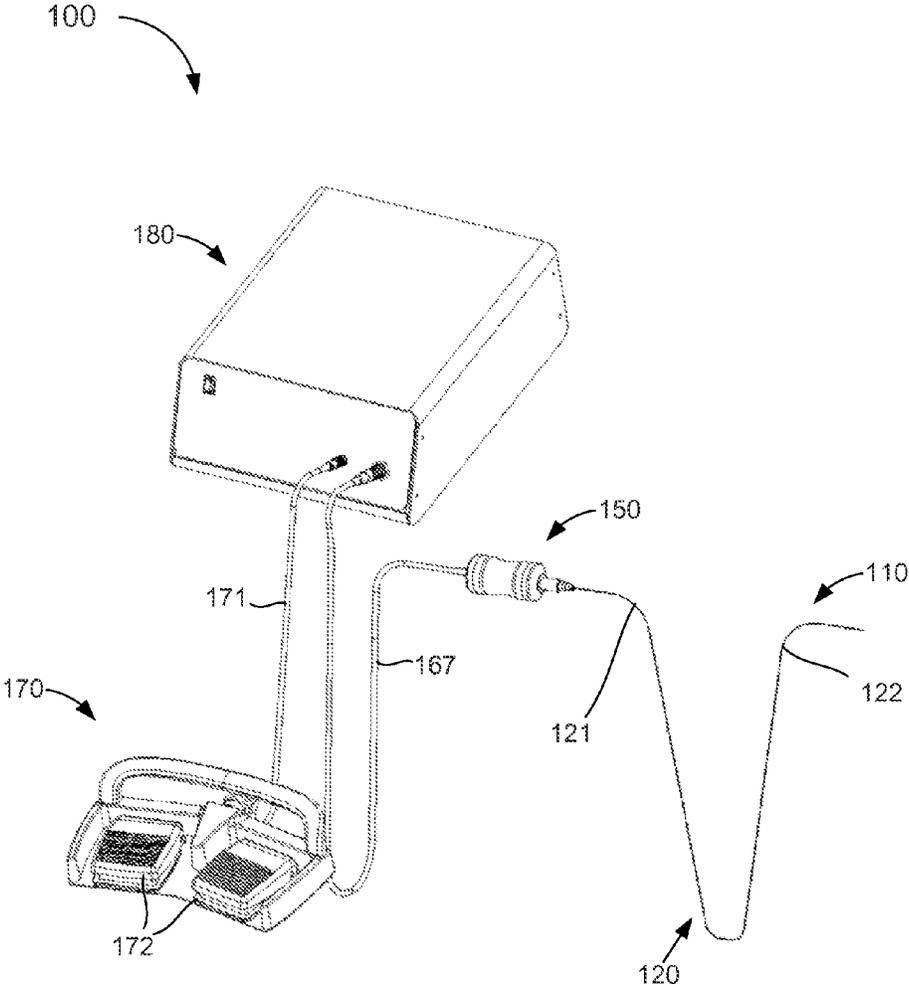


FIG. 1

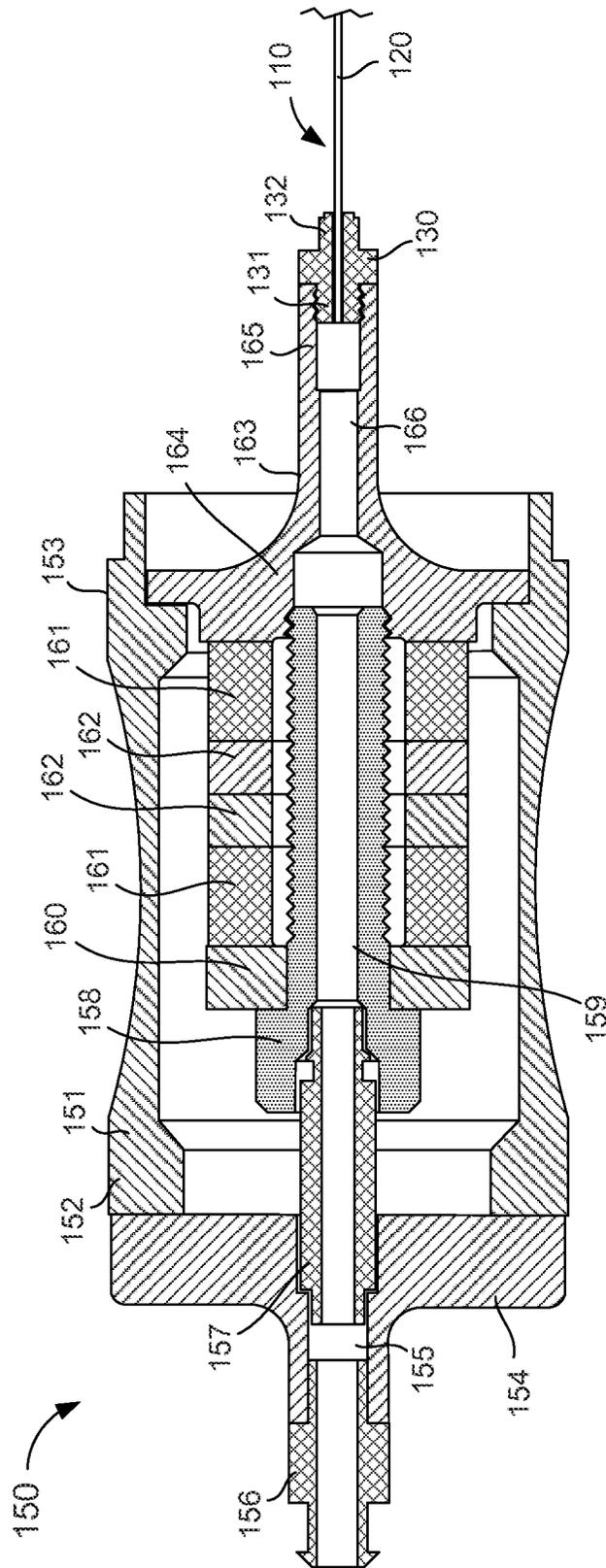


FIG. 2

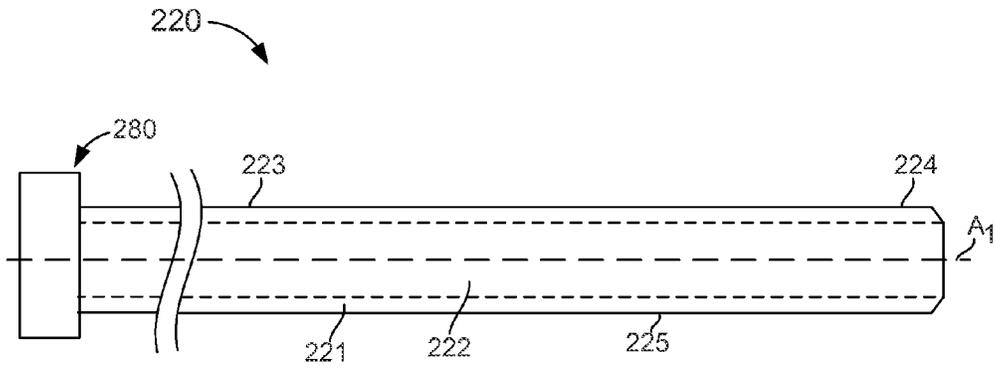


FIG. 3

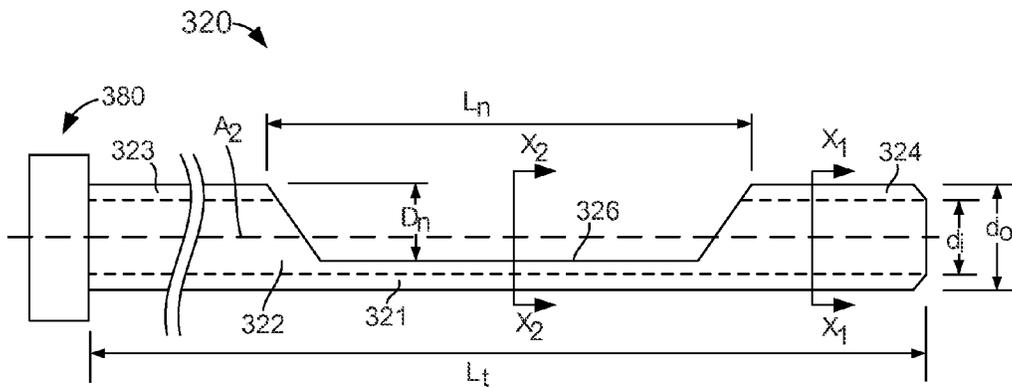


FIG. 4

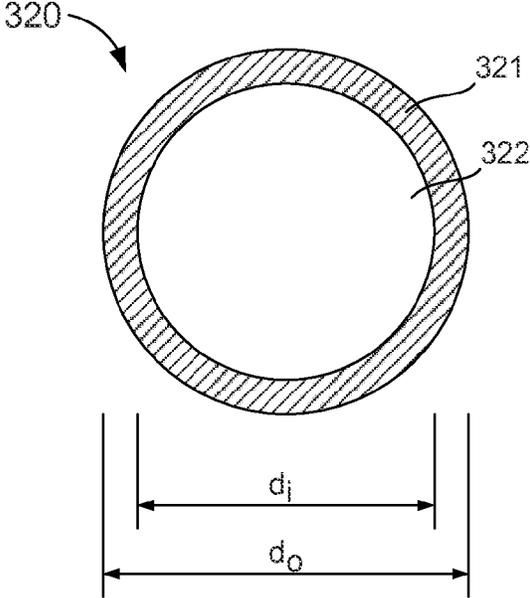


FIG. 5

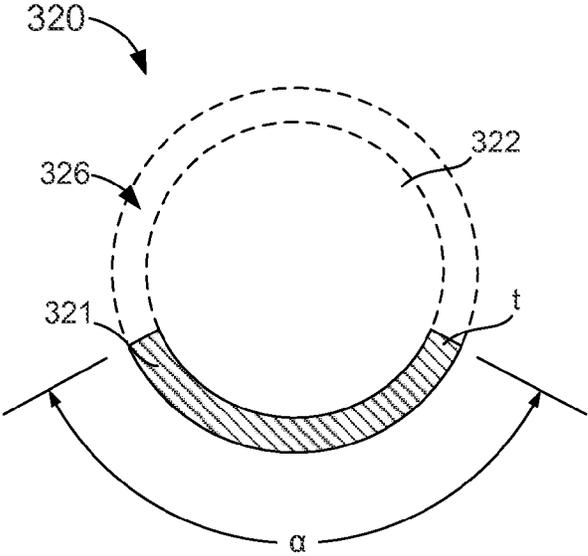


FIG. 6

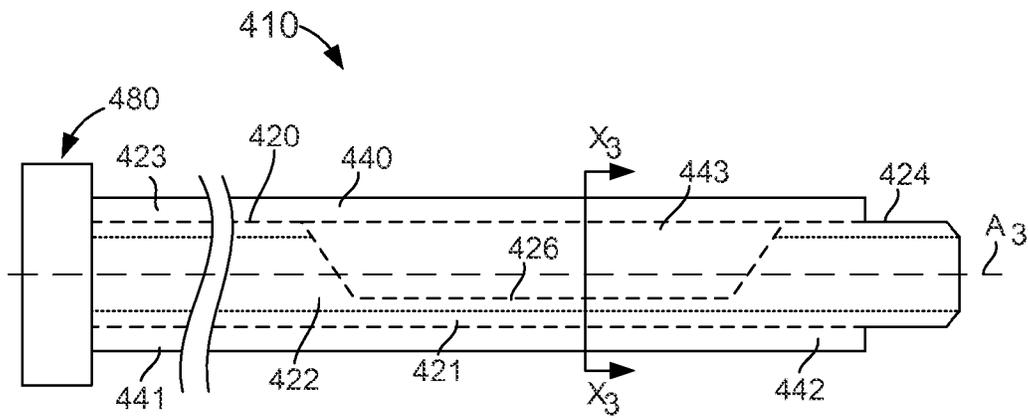


FIG. 7

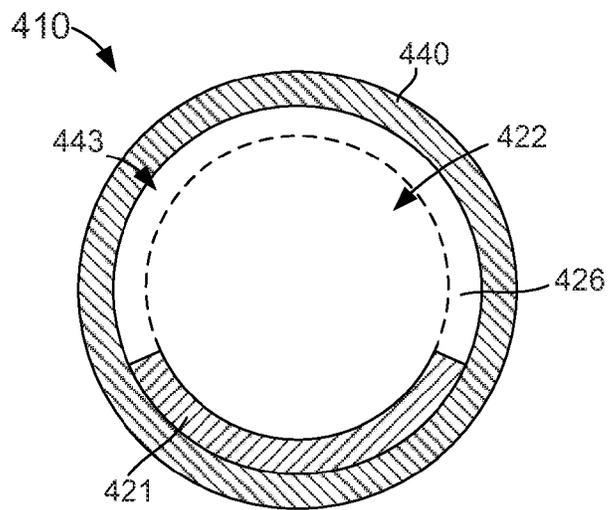


FIG. 8

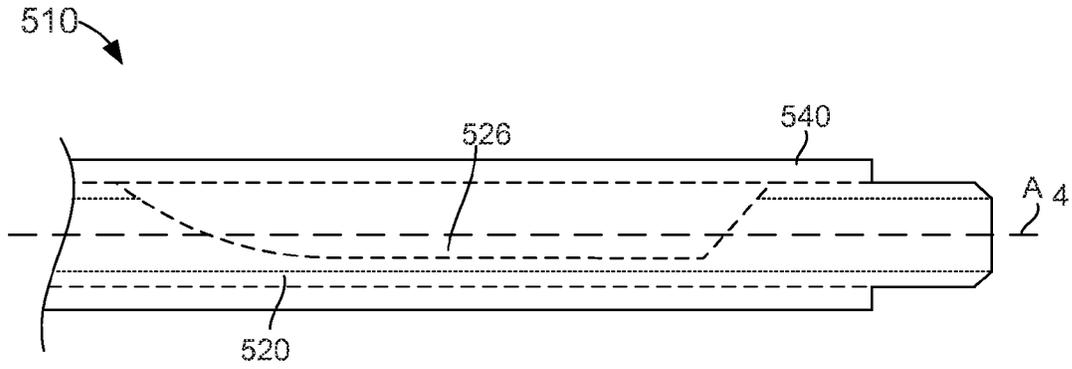


FIG. 9

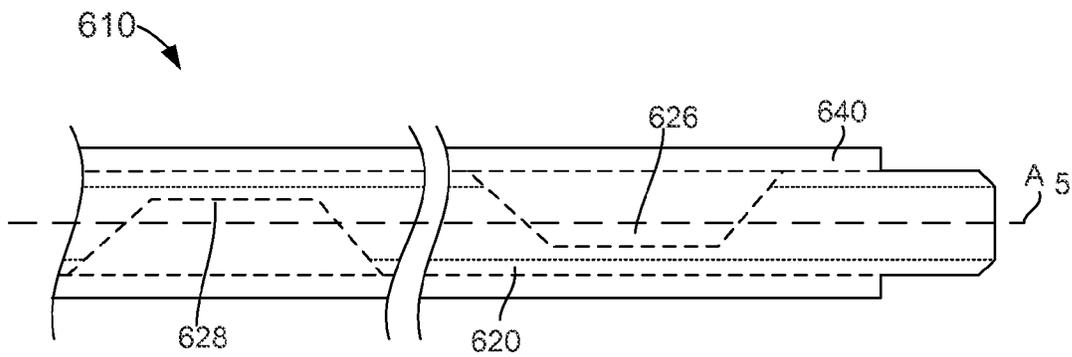


FIG. 10

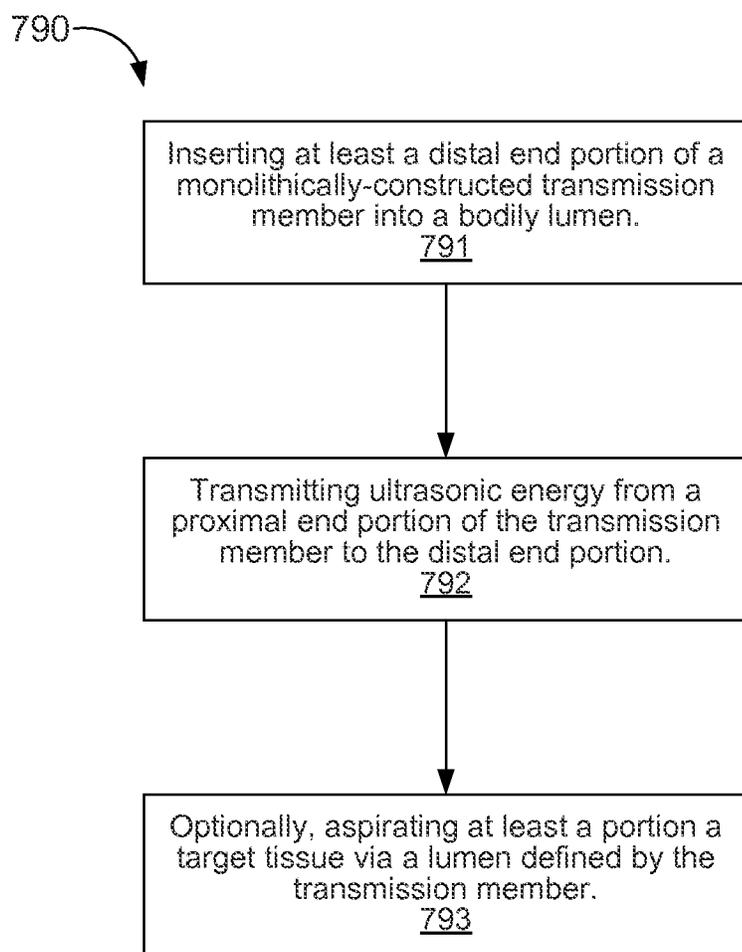


FIG. 11

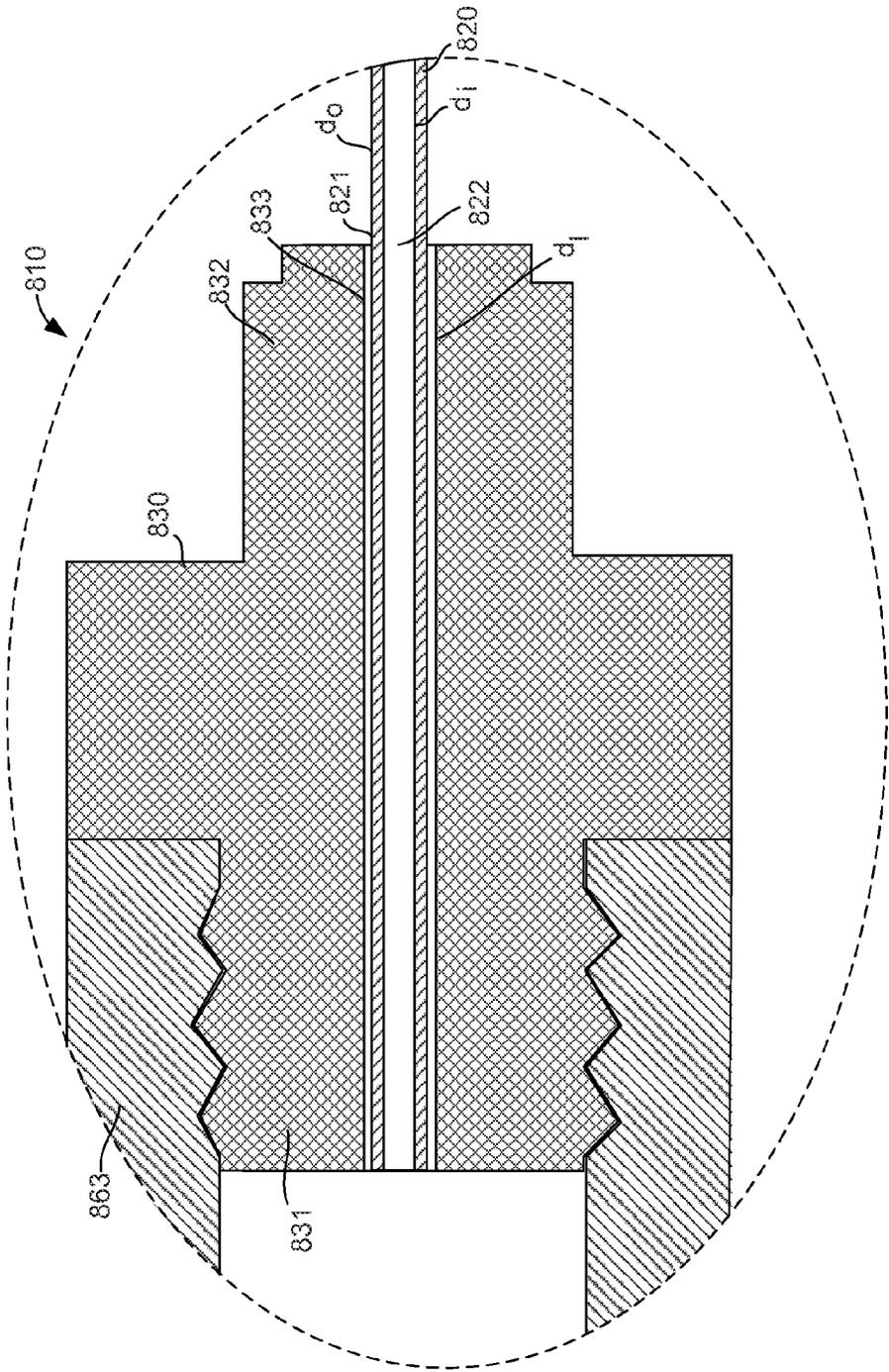


FIG. 12

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APPARATUS AND METHODS FOR TRANSFERRING ULTRASONIC ENERGY TO A BODILY TISSUE

BACKGROUND

The embodiments described herein relate generally to a device used in conjunction with an ultrasonic ablation device and, more specifically, to a transmission member configured to transfer ultrasonic energy to a bodily tissue from an ultrasonic energy source.

Known ultrasonic energy transmission systems are used in many different medical applications, such as, for example, for medical imaging, to disrupt obstructions and/or ablate bodily tissue. In known ultrasonic energy transmission systems for tissue ablation, ultrasonic energy is transferred from an ultrasonic energy source through a transducer horn and then a transmission member, such as a wire, to a distal head. Ultrasonic energy propagates through the transmission member as a periodic wave thereby causing the distal head to vibrate. Such vibrational energy can be used to ablate or otherwise disrupt bodily tissue, for example, a vascular obstruction, a kidney stone or the like. To effectively reach various sites for treatment of intravascular occlusions or regions within the urinary tract, such ultrasonic transmission members often have lengths of about 65 cm or longer.

Known ultrasonic transmission members are constructed to be flexible enough to be passed through various bodily lumens, but also with sufficient strength to transmit ultrasonic energy to the distal tip (e.g., to ablate vascular or urinary obstructions). A stronger, more durable transmission member allows for greater transmission of energy but may not be flexible or thin enough to be advanced through the vasculature to a desired treatment area. A thinner transmission member can be more flexible but is less durable and more susceptible to breakage.

In an attempt to find a balance between strength and flexibility, some known ultrasonic transmission members are tapered along a longitudinal axis of the transmission member such that the diameter of the distal end portion decreases to allow greater flexibility. For example, some known transmission members can include a diameter at the proximal end that is greater than a diameter at a distal end. Moreover, some known transmission members can include a distal tip or "head" that is welded to the reduced diameter section, and which is positioned adjacent the tissue to be treated. Such transmission members can be prone to breakage at or near the distal end of the transmission member where the cross-sectional area of the transmission member becomes smaller and/or at the discontinuous region where the two pieces are joined. Similarly stated, such breakage is generally caused by stress concentration due to transverse vibrations and fatigue. Thus, one difficulty related to transmission of ultrasonic energy through a relatively long transmission member of known design is premature wear and breakage of the transmission member.

Furthermore, the coupling of the distal head to the distal end of the transmission member results in a discontinuity between the transmission member and the distal head due to, for example, weld material, adhesive material, or the like. Such discontinuities can produce reflections of the ultrasonic wave and result in losses of ultrasonic energy. To overcome the energy losses and inefficiency in energy transfer due to reflections or the like, some known systems increase the level of ultrasonic energy transferred through the transmission member. Similarly stated, some known systems apply a high level of energy at the proximal end portion to overcome the

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inefficiencies of the transmission member (e.g., at the distal end). However, the increase in the ultrasound energy transferred through the transmission member can increase stress on the transmission member and, consequently, can result in premature fatigue and breakage. In addition to the loss of transmission efficiency, known transmission members constructed of multiple pieces are expensive and can be complicated to manufacture.

Thus, a need exists for an improved apparatus and methods for transferring ultrasonic energy from an ultrasonic energy source to a bodily tissue.

SUMMARY

Devices and methods of use of a transmission device for use with an ultrasonic ablation system are described herein. In some embodiments, an apparatus includes a monolithically constructed transmission member that defines a lumen along a longitudinal axis. The transmission member includes a first portion, a second portion, and a third portion. The first portion can be coupled to an ultrasonic energy source. The second portion is configured to be disposed within the body to transfer ultrasonic energy from the first portion into the bodily tissue. The third portion is disposed between the first portion and the second portion and defines a cross-sectional moment of inertia that is less than at least one of a cross-sectional area moment of inertia of the first portion or a cross-sectional moment of inertia of the second portion.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an illustration of a system for delivering ultrasonic energy to a bodily tissue according to an embodiment.

FIG. 2 is a cross-sectional view of an ultrasonic transducer included in the system of FIG. 1.

FIG. 3 is a schematic illustration of a transmission member, according to an embodiment.

FIG. 4 is an illustration of a transmission member, according to an embodiment.

FIG. 5 is a cross-sectional view of the transmission member of FIG. 4 taken along the line X_1-X_1 .

FIG. 6 is a cross-sectional view of the transmission member of FIG. 4 taken along the line X_2-X_2 .

FIG. 7 is an illustration of a probe assembly according to an embodiment.

FIG. 8 is a cross-sectional view of the probe assembly of FIG. 7 taken along the line X_3-X_3 .

FIG. 9 is a schematic illustration of a probe assembly according to an embodiment.

FIG. 10 is a schematic illustration of a probe assembly according to an embodiment.

FIG. 11 is a flowchart illustrating a method for transferring ultrasonic energy to a bodily tissue.

FIG. 12 is an enlarged view of a portion of a probe assembly according to an embodiment coupled to a transducer horn.

DETAILED DESCRIPTION

Devices and methods of use of a transmission device for use with an ultrasonic ablation system are described herein. In some embodiments, an apparatus includes a monolithically constructed transmission member that defines a lumen along a longitudinal axis. The transmission member includes a first portion, a second portion, and a third portion. The first portion can be coupled to an ultrasonic energy source. The second portion is configured to be disposed within the body (e.g., adjacent to or in contact with a bodily tissue) to transfer

ultrasonic energy from a first portion into the bodily tissue. The third portion is disposed between the first portion and the second portion and defines a cross-sectional moment of inertia that is less than at least one of a cross-sectional area moment of inertia of the first portion or a cross-sectional moment of inertia of the second portion.

In some embodiments, an apparatus includes a transmission member and an outer member coupled thereto. The transmission member includes a first end portion and a second end portion, and defines a lumen therethrough. The transmission member is configured to transfer ultrasonic energy from a first end portion to a second end portion. The transmission member further includes a sidewall that defines an elongated opening therethrough that is in fluid communication with the lumen. At least a portion of the outer member is disposed about the elongated opening of the transmission member such that the lumen is substantially fluidically isolated from a region outside of the outer member. In some embodiments, the outer member is fixedly coupled to the transmission member, for example, by a weld, an adhesive or the like. In some embodiments, the transmission member is monolithically constructed.

In some embodiments, a kit includes an ultrasonic transducer assembly and multiple transmission members each configured to be coupled to the ultrasonic transducer assembly. Each transmission member from the multiple transmission members has a diameter substantially the same as the diameter of each of the other transmission members. A first transmission member included in the multiple transmission members defines a flexural stiffness that is different than a flexural stiffness of a second transmission member included in the multiple transmission members. In some embodiments, for example, the first transmission member can define a cross-sectional area moment of inertia that is different than a cross-sectional area moment of inertia defined by the second transmission member.

In some embodiments, a method includes inserting at least a distal end portion of a monolithically constructed transmission member into a bodily lumen. The transmission member includes a proximal end portion and a flexible portion. The proximal end portion is coupled to an ultrasonic energy source. The flexible portion is disposed between the proximal end portion and the distal end portion and defines a cross-sectional area moment of inertia that is less than at least one of a cross-sectional area moment of inertia of the proximal end portion or a cross-sectional area moment of inertia of the distal end portion. The method further includes transmitting ultrasonic energy from the proximal end portion towards the distal end portion such that a portion of the ultrasonic energy is delivered to a target tissue within the bodily lumen. In some embodiments, the flexible portion can define a cross-sectional area moment of inertia that is different than a cross-sectional area moment of inertia defined by the proximal end portion and/or the distal end portion.

As used in this specification, the terms “proximal” and “distal” refer to the direction closer to and away from, respectively, a user who would place the device into contact with a patient. Thus, for example, the end of a device first touching the body of the patient would be the distal end, while the opposite end of the device (e.g., the end of the device being manipulated by the user) would be the proximal end of the device.

As used herein, the terms “about” and “approximately” generally mean plus or minus 10% of the value stated. For example, about 0.5 would include 0.45 and 0.55, about 10 would include 9 to 11, about 1000 would include 900 to 1100.

As used herein, the term “set” can refer to multiple features or a singular feature with multiple parts. For example, when referring to set of walls, the set of walls can be considered as one wall with multiple portions, or the set of walls can be considered as multiple, distinct walls. Thus, a monolithically-constructed item can include a set of walls. Such a set of walls can include, for example, multiple portions that are either continuous or discontinuous from each other. A set of walls can also be fabricated from multiple items that are produced separately and are later joined together (e.g., via a weld, an adhesive, or any suitable method).

As used herein, the term “target tissue” refers to an internal or external tissue of or within a patient to which ultrasonic energy ablation techniques are applied. For example, a target tissue can be cancer cells, tumor cells, lesions, vascular occlusions, thrombosis, calculi, uterine fibroids, bone metastases, adenomyosis, or any other bodily tissue. Furthermore, the presented examples, of target tissues are not an exhaustive list of suitable target tissues. Thus, the ultrasonic energy systems described herein are not limited to the treatment of the aforementioned tissues and can be used on any suitable bodily tissue. Moreover, a “target tissue” can also include an artificial substance within or associated with a body, such as for example, a stent, a portion of an artificial tube, a fastener within the body or the like. Thus, for example, the ultrasonic energy systems described herein can be used on or within a stent or artificial bypass graft.

As used herein, the term “stiffness” relates to an object’s resistance to deflection, deformation, and/or displacement produced by an applied force, and is generally understood to be the opposite of the object’s “flexibility.” For example, a wall of a tube with greater stiffness is more resistant to deflection, deformation and/or displacement when exposed to a force than a wall of a tube having a lower stiffness. Similarly stated, a tube having a higher stiffness can be characterized as being more rigid than a tube having a lower stiffness. Stiffness can be characterized in terms of the amount of force applied to the object and the resulting distance through which a first portion of the object deflects, deforms, and/or displaces with respect to a second portion of the object. When characterizing the stiffness of an object, the deflected distance may be measured as the deflection of a portion of the object different than the portion of the object to which the force is directly applied. Said another way, in some objects, the point of deflection is distinct from the point where force is applied.

Stiffness (and therefore, flexibility) is an extensive property of the object being described, and thus is dependent upon the material from which the object is formed as well as certain physical characteristics of the object (e.g., cross-sectional shape, length, boundary conditions, etc.). For example, the stiffness of an object can be increased or decreased by selectively including in the object a material having a desired modulus of elasticity, flexural modulus and/or hardness. The modulus of elasticity is an intensive property of (i.e., is intrinsic to) the constituent material and describes an object’s tendency to elastically (i.e., non-permanently) deform in response to an applied force. A material having a high modulus of elasticity will not deflect as much as a material having a low modulus of elasticity in the presence of an equally applied stress. Thus, the stiffness of the object can be decreased, for example, by introducing into the object and/or constructing the object of a material having a relatively low modulus of elasticity.

The stiffness of an object can also be increased or decreased by changing a physical characteristic of the object, such as the shape or cross-sectional area of the object. For example, an object having a length and a cross-sectional area

may have a greater stiffness than an object having an identical length but a smaller cross-sectional area. As another example, the stiffness of an object can be reduced by including one or more stress concentration risers (or discontinuous boundaries) that cause deformation to occur under a lower stress and/or at a particular location of the object. Thus, the stiffness of the object can be decreased by decreasing and/or changing the shape of the object.

The stiffness (or inversely, the flexibility) of an elongated object, such as a catheter or tube can be characterized by its flexural stiffness. The flexural stiffness of an object can be used to characterize the ease with which the object deflects under a given force (e.g., the ease with which the object deflects when the object is moved along a tortuous path within the body). The flexural stiffness of an object, such as a catheter, transmission member or the like, can be mathematically expressed as shown below:

$$k = \frac{3EI}{L^3}$$

where k is the flexural stiffness of the object, E is the modulus of elasticity of the material from which the object is constructed, I is the area moment of inertia of the object (defined below), and L is the length of the object.

As used herein, the terms “cross-sectional area moment of inertia,” “area moment of inertia,” and/or “second moment of area” relate to an object’s resistance to deflection or displacement around an axis that lies in a cross-sectional plane. The area moment of inertia is dependent on the cross-sectional area and/or shape of the object and can be mathematically expressed as a function of a cross-section of the object. The area moment of inertia of an object (e.g., such as the tubes disclosed herein) is described having units of length to the fourth power (e.g., in⁴, mm⁴, cm⁴, etc.). In this manner, the “area moment of inertia” is differentiated from the “moment of inertia” or “mass moment of inertia” which is expressed having units of mass times units of length to the second power (e.g., kg*m², lb_m*ft², etc.).

Two mathematical formulas are used herein to define an area moment of inertia for a substantially annular cross-sectional shape and for a substantially arc-shaped cross-sectional shape. The area moment of inertia for the annular cross-section shape is expressed below as:

$$I = \frac{\pi(d_o^4 - d_i^4)}{64}$$

where d_o is an outside diameter of the annulus and d_i is an inner diameter of the annulus.

The area moment of inertia for an arced cross-sectional shape is expressed below as:

$$I = \frac{r^3 t}{2} [\alpha + \cos(\alpha - \frac{\pi}{2})]$$

where r is the radius of the arc, t is the thickness of the arc segment (e.g., d_o-d_i), and α is the subtended angle of the radius. For continuity with the area moment of inertia equation for the annular cross-section, the equation can be expressed as shown below:

$$I = \frac{d_i^3 (d_o - d_i)}{16} [\alpha + \cos(\alpha - \frac{\pi}{2})]$$

Embodiments described herein relate to ultrasonic energy ablation systems. In such systems a transmission member can be operably coupled to an ultrasonic energy source to deliver ultrasonic energy to a target bodily tissue. For example, FIG. 1 is an illustration of an ultrasonic energy ablation system 100, according to an embodiment. The ultrasonic energy ablation system 100 (also referred to herein as “ultrasonic system” or simply “system”) includes an ultrasonic generator 180, a foot switch 170, an ultrasonic transducer assembly 150, and a probe assembly 110. The ultrasonic generator 180 (or “generator”) can be any suitable generator configured to generate, control, amplify, and/or transfer an electric signal (e.g., a voltage) to the transducer assembly 150.

The ultrasonic generator 180 includes at least a processor, a memory and the circuitry (not shown in FIG. 1) to produce an electronic signal (i.e., a current and a voltage) having the desired characteristics that can be received by the ultrasonic transducer assembly 150 and converted into ultrasonic energy. In some embodiments, the ultrasonic generator 180 can be electrically coupled to (e.g., “plugged into”) an electric receptacle such that the ultrasonic generator 180 receives a flow of electric current. For example, in some embodiments, the ultrasonic generator 180 can be plugged into a wall outlet that delivers alternating current (AC) electrical power at a given voltage (e.g., 120V, 230V, or other suitable voltage) and a given frequency (e.g., 60 Hz, 50 Hz, or other suitable frequency).

Although not shown in FIG. 1, the ultrasonic generator 180 includes the electronic circuitry, hardware, firmware and/or instructions to cause the ultrasonic generator 180 to act as a frequency inverter and/or voltage booster. In this manner, the ultrasonic generator 180 can produce and/or output a voltage to the transducer assembly 150 having the desired characteristics to produce the desired ultrasonic energy output. For example, in some embodiments, the ultrasonic generator 180 can receive AC electrical power at a frequency of approximately 60 Hz and a voltage of approximately 120V and convert the voltage to a frequency up to approximately 20,000 Hz to 35,000 Hz with a voltage of approximately 500-1500 VAC (RMS). Thus, the ultrasonic generator 180 can supply the transducer assembly 150 with a flow of AC electrical power having an ultrasonic frequency.

As shown in FIG. 1, the system 100 includes the foot switch 170 that is in electric communication with the ultrasonic generator 180 via a foot switch cable 171. The foot switch 170 includes a set of pedals 172 (e.g., two pedals as shown) that are operative in controlling the delivery of the ultrasonic electrical energy supplied to the ultrasonic transducer assembly 150. For example, in some embodiments, a user (e.g., a physician, technician, etc.) can engage and/or depress one or more of the pedals 172 to control the current supplied to the ultrasonic transducer assembly 150 such that, in turn, the probe assembly 110 delivers the desired ultrasonic energy to the bodily tissue, as further described in detail herein.

The transducer assembly 150 is in electric communication with the ultrasonic generator 180 via a transducer cable 167. In this manner, the transducer assembly 150 can receive an electrical signal (i.e., voltage and current) from the ultrasonic generator 180. The transducer assembly 150 is configured to produce and amplify the desired ultrasonic energy via a set of piezoelectric members 162 (i.e., piezoelectric rings) and an

ultrasonic horn **163** (see e.g., FIG. 2), and transfer the ultrasonic energy to the probe assembly **110** and/or the transmission member **120**. The transducer assembly **150** can be any suitable assembly of the types shown and described herein.

For example, in some embodiments, as shown in FIG. 2, the transducer assembly **150** includes a housing **151** having a proximal end portion **152** and a distal end portion **153**. The housing **151** is configured to house or otherwise enclose at least a portion of a flow tube **157**, a bolt **158**, a back plate **160**, a set of insulators **161**, a set of piezoelectric rings **162**, and a transducer horn **163**.

The proximal end portion **152** of the housing **151** is coupled to a proximal cover **154** (e.g., via an adhesive, a press or friction fit, a threaded coupling, a mechanical fastener, or the like). The proximal cover **154** defines an opening **155** such that the proximal cover **154** can receive a portion of a connector **156** (e.g., a luer connector) on a proximal side thereof (e.g., substantially outside the housing **151**) and a portion of the flow tube **157** on a distal side thereof (e.g., substantially inside the housing **151**). Expanding further, the proximal cover **154** can receive the connector **156** and the flow tube **157** such that the proximal cover **154** forms a substantially fluid tight seal with the connector **156** and the flow tube **157**. In this manner, a vacuum can be applied via the connector **156** to irrigate and/or aspirate the region of the body within which the probe assembly **110** is disposed. Similarly stated, this arrangement results in the connector **156** being placed in fluid communication with the lumen **122** defined by the transmission member **120**.

The distal end portion **153** of the housing **151** is configured to receive the transducer horn **163** such that the transducer horn **163** is coupled to an inner surface of the housing **151**. More specifically, the transducer horn **163** can be disposed at least partially within the housing **151** such that the transducer horn **163** can be moved relative to the housing **151** (e.g., when amplifying the ultrasonic energy), but not moved out of the housing **151** during normal use. The transducer horn **163** includes a proximal end portion **164** and a distal end portion **165** and defines a lumen **166** therethrough. The lumen **166** is configured to receive a portion of the bolt **158** at the proximal end portion **164** of the transducer horn **163** and a portion of the probe assembly **120** at the distal end portion **165** of the transducer horn **163**, both of which are described in further detail herein.

As shown in FIG. 2, the back plate **160**, the insulators **161**, and the piezoelectric rings **162** are disposed within the housing **151** and about the bolt **158**. More specifically, the arrangement of the back plate **160**, the insulators **161**, and the piezoelectric rings **162** is such that the back plate **160** is disposed proximal to the insulators **161** and the piezoelectric rings **162**. The piezoelectric rings **162** are each disposed between the insulators **161**. Similarly stated, a first insulator **161** is disposed proximal to the piezoelectric rings **162** and a second insulator **161** is disposed distal to the piezoelectric rings **162**. The piezoelectric rings **162** are in electric communication (e.g., via wires not shown in FIGS. 1 and 2) with the ultrasonic generator **180**, as described in further detail herein.

As shown in FIG. 2, a portion of the bolt **158** is configured to be disposed within the lumen **166** defined by the transducer horn **163**. More specifically, the portion of the bolt **158** forms a threaded fit with an inner surface of the transducer horn **163** that defines the lumen **166**. In this manner, the bolt **158** can be advanced within the lumen **166** such that the bolt **158** exerts a compressive force on the backing plate **160**, the insulators **161**, and the piezoelectric rings **162**. Thus, the backing plate **160**, the insulators **161**, and the piezoelectric rings **162** are retained between a head of the bolt **158** (e.g., at the proximal

end) and a proximal surface of the transducer horn **163**. The torque applied to the bolt and/or the clamping force exerted between the head of the bolt **158** and the proximal surface of the transducer horn **163** is such that that the deviation of the transducer natural frequency deviation is within ten percent from nominal. Therefore, in use, the piezoelectric rings **162** can vibrate and/or move the transducer horn **163**, as further described herein.

The bolt **158** further defines a lumen **159** such that a proximal end portion of the bolt **158** can receive a distal end portion of the flow tube **157**. In this manner, the lumen **159** defined by the bolt **158** and the flow tube **157** collectively place the lumen **166** defined by the transducer horn **163** in fluid communication with the connector **156**. Thus, the lumen **166** of the transducer horn **163** can be placed in fluid communication with a volume substantially outside of the proximal end of the housing **151**.

As shown in FIGS. 1 and 2, the probe assembly **110** includes at least a transmission member **120** and a coupler **130**. The coupler **130** includes a proximal end portion **131** and a distal end portion **132** and defines a lumen **133** that extends therethrough. The proximal end portion **131** of the coupler **130** is disposed within the lumen **166** at the distal end portion **165** of the transducer horn **163** and forms a threaded fit with the inner surface of the transducer horn **163** that defines the lumen **166**. The distal end portion **131** of the coupler **130** is configured to receive a portion of the transmission member **120** to fixedly couple the transmission member **120** to the coupler **130**. In this manner, the probe assembly **110** can be removably coupled to the transducer assembly **150** via the coupler.

The transmission member **120** is an elongate tube having a proximal end portion **121** and a distal end portion **122**. The transmission member **120** can be any suitable shape, size, or configuration and is described in further detail herein with respect to specific embodiments. In some embodiments, the transmission member **120** can optionally include any suitable feature configured to increase the flexibility (e.g., decrease the stiffness) of at least a portion of the transmission member **120**, thereby facilitating the passage of the transmission member **120** through a tortuous lumen within a patient (e.g., a urinary tract, a vein, artery, etc.). For example, in some embodiments, a portion of the transmission member **120** can be formed from a material of lower stiffness than a different portion of the transmission member **120** formed from a material of greater stiffness. In some embodiments, the stiffness of at least a portion of the transmission member **120** can be reduced by defining an opening (e.g., notch, a groove, a channel, a cutout, or the like), thereby reducing the area moment of inertia of the portion of the transmission member **120**, as described herein with respect to specific embodiments.

In use, a user (e.g., a surgeon, a technician, physician, etc.) can operate the ultrasonic system **100** to deliver ultrasonic energy to a target bodily tissue within a patient. The user can, for example, engage the pedals **172** of the foot switch **170** such that the ultrasonic generator **180** generates an alternating current (AC) and voltage with a desired ultrasonic frequency (e.g., 20,000 Hz). In this manner, the ultrasonic generator **180** can supply AC electric power to the piezoelectric rings **162**. The AC electric power can urge the piezoelectric rings **162** to oscillate (e.g., expand, contract, or otherwise deform) at the desired frequency, which, in turn, causes the transducer horn **163** to move relative to the housing **151**. Thus, with the probe assembly **110** coupled to the transducer horn **163**, the movement of the transducer horn **163** vibrates and/or moves the probe assembly **110**. In this manner, the distal end portion **122**

of the transmission member **120** can be disposed with a portion of the patient adjacent to a target tissue such that the transmission member **120** transfers at least a portion of the ultrasonic energy to the target tissue (not shown in FIGS. **1** and **2**). For example, in some embodiments, a distal tip of the transmission member **120** can impact a target tissue such as, for example, to break apart the occlusion. In some embodiments, the movement of the distal end portion **122** of the transmission member **120** is such that cavitations occur within the portion of the patient. In this manner, the cavitations can further break apart a target tissue. In some embodiments, the ultrasonic system **100** can optionally be used to aspirate and/or to supply irrigation to a target tissue site.

While described above in a general way, an ultrasonic energy system, such as the ultrasonic energy system **100**, can include any suitable probe or transmission member of the types shown herein having increased flexibility to facilitate the passage of the transmission member through a tortuous lumen within a patient. For example, in some embodiments, a transmission member can have a suitable flexibility such that at least a portion of the transmission member can elastically (e.g., not permanently) deform within the tortuous anatomical structure. For example, FIG. **3** is a schematic illustration of a transmission member **220**, according to an embodiment. The transmission member **220** can be included in any suitable ultrasonic energy system shown and described herein, such as, for example, the system **100** described above with reference to FIGS. **1** and **2**. The transmission member **220** is a monolithically-constructed elongate member including a side wall **221** and defining a lumen **222** along a longitudinal axis A_1 . In this manner, the transmission member **220** can provide aspiration from and/or irrigation (via the lumen **222**, and the connecting lumens of any component to which the transmission member **220** is coupled) to a target tissue site during an ultrasonic procedure.

As shown in FIG. **3**, the transmission member **220** includes a first portion **223**, a second portion **224**, and a third portion **225**. The first portion **223** can be, for example, a proximal end portion, and can be at least operably coupled to an ultrasonic energy source **280**, such as for example, the ultrasonic generator **180** and/or the transducer assembly **150** described above. For example, in some embodiments, the first portion **223** can be disposed within a lumen of a coupler member (not shown), as described above with reference to FIG. **2**. In such embodiments, the coupler member can be coupled to the ultrasonic energy source **280**, thus, operably coupling the transmission member **220** to the ultrasonic energy source **280**. The second portion **224** can be, for example, a distal end portion of the transmission member **220**, and can be disposed within a body (not shown) to transfer ultrasonic energy from the first portion **223** into a bodily tissue.

The third portion **225** is disposed between the first portion **223** and the second portion **224**. The third portion **225** defines a cross-sectional area moment of inertia that is less than a cross-sectional area moment of inertia of the first portion **223** and/or the second portion **224**. In this manner, the transmission member **220** has a suitable flexural stiffness to be disposed along and/or within a tortuous path within the body such that the transmission member **220** efficiently and reliably transmits ultrasonic energy from the first portion **223** to the second portion **224**. More particularly, the lower area moment of inertia of third portion **225** allows the third portion **225** to elastically deform more easily than the first portion **223** and/or the second portion **224**. Said another way, the third portion **225** can bend (e.g., elastically) more easily about an

axis that is perpendicular to the longitudinal axis A_1 of the transmission member **220** than can the first portion **223** and/or the second portion **224**.

Moreover, the greater flexural stiffness of the first portion **223** and/or the second portion **224** can reduce losses of ultrasonic energy transmitted through the transmission member **220** that are associated with more flexible materials and/or members. Similarly stated, the spatial variation in the area moment of inertia results higher transmission efficiency than would otherwise be obtained when forming the transmission member **220** to have a constant, lower flexural stiffness. Because the transmission member **220** is monolithically constructed, it is devoid of material interfaces that are known to cause reflection of the ultrasonic energy waves (and thereby inefficient transfer of the same). Additionally, because the transmission member **220** is monolithically constructed, there is a reduced likelihood that the transmission member **220** will fail during use as a result of discontinuities and/or stress concentration risers associated with the joining of separately constructed pieces.

The transmission member **220** can be formed from any suitable material such as, for example, Type 304 stainless steel, Type 316 stainless steel, nickel titanium alloy (nitinol), or any other super elastic metal or metal alloy. In some embodiments, the first portion **223**, the second portion **224**, and/or the third portion **225** can be formed from a material that is dissimilar from the material of the other portions. For example, in some embodiments, the first portion **223** and the second portion **224** can be formed from a first material and the third portion **225** can be formed from a second material. In such embodiments, the first material can have a modulus of elasticity that is substantially greater than the modulus of elasticity of the second material. For example, in some embodiments, the first portion **223** and the second portion **224** can be formed from Type 304 stainless steel and the third portion **225** can be formed from nitinol. In this manner, the first portion **223** and the second portion **224** can have a higher rigidity than that of the third portion **225**. Similarly stated, the third portion **225** can have a lower flexural stiffness (defined above) than the flexural stiffness of the first portion **223** and the second portion **224**.

In other embodiments, the monolithically-formed transmission member **220** can be formed from a substantially uniform material (e.g., a single material). Similarly stated, in some embodiments, the flexural stiffness of the first portion **223** and the second portion **224** can be greater than the flexural stiffness of the third portion **225** while being formed from the same material. In such embodiments, the spatial variation in the area moment of inertia is achieved by varying the cross-sectional size and/or shape of the transmission member **220** along its longitudinal axis A_1 . For example, in some embodiments, the transmission member **220** can be substantially cylindrical and can have a uniform outer diameter along a length of the transmission member **220**. Similarly stated, the first portion **223**, the second portion **224**, and the third portion **225** can each have substantially the same outer diameters. In such embodiments, the first portion **223**, the second portion **224**, and the third portion **225** can have a dissimilar inner diameter. For example, the first portion **223** and/or the second portion **224** can have an inner diameter that is smaller (resulting in a thicker sidewall **221**) than the inner diameter of the third portion **225**. Thus, the first portion **223** and/or the second portion **224** have an area moment of inertia that is greater than the area moment of inertia of the third portion **225**. In this manner, the first portion **223** and/or the second portion **224** have a flexural stiffness that is greater than the flexural stiffness of the third portion **225**.

In other embodiments, the outer diameter of the first portion 223 and/or the outer diameter of the second portion 224 can be greater than the outer diameter of the third portion 225. Thus, by maintaining a similar inner diameter, the first portion 223 and/or the second portion 224 can have a greater area moment of inertia than the area moment of inertia of the third portion 225. In this manner, the first portion 223 and/or the second portion 224 have a flexural stiffness greater than the flexural stiffness of the third portion 225.

In yet other embodiments, the nominal outer diameter and the nominal inner diameter of the transmission member can be substantially constant. In such embodiments, a portion of a transmission member can include and/or define a discontinuity or change in cross-sectional shape configured to reduce the area moment of inertia of at least the portion of the transmission member. For example, FIGS. 4-6 are schematic illustrations of a transmission member 320, according to an embodiment. The transmission member 320 can be included in any suitable ultrasonic energy system such as, for example, the system 100 described above with reference to FIGS. 1 and 2. The transmission member 320 is a monolithically-constructed elongate member including a side wall 321 and defining a lumen 322 along a longitudinal axis A_2 . In this manner, the transmission member 320 can provide aspiration from and/or irrigation (via the lumen 322) to a target tissue site during an ultrasonic procedure.

The transmission member 320 includes a first portion 323 and a second portion 324. The first portion 323 can be, for example, a proximal end portion and can be at least operably coupled to an ultrasonic energy source 380, such as for example, the ultrasonic generator 180 and/or the transducer assembly 150 described above. For example, in some embodiments, the first portion 323 can be disposed within a lumen of a coupler member (not shown), as described above with reference to FIG. 2. In such embodiments, the coupler member can be coupled to the ultrasonic energy source 380, thus, operably coupling the transmission member 220 to the ultrasonic energy source 380. The second portion 324 can be, for example, a distal end portion of the transmission member 320, and can be disposed within a body (not shown) to transfer ultrasonic energy from the first portion 223 into a bodily tissue.

The transmission member 320 can be substantially cylindrical and can have a uniform outer diameter d_o along a length L_t of the transmission member 320. The walls 321 of the transmission member 321 can be configured such that the transmission member 320 also has a substantially uniform inner diameter d_i . Similarly stated, the first portion 323 and the second portion 324 can each have substantially the same outer diameters and substantially the same inner diameters.

The transmission member 320 can be any suitable size. For example, in some embodiments, the walls 321 have a thickness t of approximately 0.006 inches, the outer diameter d_o is approximately 0.032 inches, and the inner diameter d_i is approximately 0.020 inches. In other embodiments, the outer diameter d_o of the transmission member 320 can be between approximately 0.014 and 0.050 inches and the inner diameter d_i can be between approximately 0.010 and 0.040 inches. In some embodiments, the length L_t of the transmission member 320 is approximately 57.5 inches.

The transmission member 320 further defines an elongate opening 326 (e.g., a notch, a groove, a channel, a cutout, etc.) along at least a portion of the longitudinal axis A_2 that is in fluid communication with the lumen 322. The opening 326 can be any suitable shape, size, or configuration. For example, as shown in FIG. 4, the opening 326 can be substantially symmetrical relative to a plane perpendicular to the longitu-

dinal axis A_2 . Moreover, the transmission member 320 can be configured such that the elongate opening 326 has a desired length L_n and a desired depth D . For example, in some embodiments, the length L_n of the opening 326 can be approximately 5 times the outer diameter d_o of the transmission member. In other embodiments, the length L_n of the opening 326 can be greater than 5 times the outer diameter d_o of the transmission member. In still other embodiments, the length L_n of the opening 326 can be related to the length L_t of the transmission member 320. For example, in some embodiments, the length L_n of the opening 326 can be between 40 percent and 90 percent of the length L_t of the transmission member 320.

The depth D_n of the opening 326 can be, for example, at least half of the outer diameter d_o of the transmission member 320 (resulting in a subtended angle, as described below, of approximately 180 degrees). In other embodiments, the depth D_n of the opening 326 can be approximately 0.016 inches. In other embodiments, the depth D_n of the opening 326 can be between approximately 0.2 to 0.8 times the outer diameter d_o of the transmission member 320.

As shown in FIGS. 5 and 6, the cross-sectional shape of the transmission member 320 is substantially changed at positions along the longitudinal axis A_2 . More specifically, FIG. 5 illustrates a cross-sectional shape of the transmission member 320 taken at a location along the longitudinal axis A_2 away from a region of the opening 326, and FIG. 6 illustrates a substantially arced cross-sectional shape of the transmission member 320 taken at a location along the longitudinal axis A_2 that includes the opening 326. As shown in FIG. 6, the presence of the opening 326 results in the transmission member 320 having an arc-shaped cross-sectional shape along a portion thereof. The transmission member 320 can be configured such that the arced cross-sectional shape has a subtended angle α of between approximately 20 degrees and approximately 120 degrees. In other embodiments, the transmission member 320 is configured such that the arced cross-sectional shape has a subtended angle α of up to approximately 180 degrees.

The opening 326 can be such that the transmission member 320 has an area moment of inertia at a position along the longitudinal axis A_2 having the arced cross-sectional shape that is substantially less than an area moment of inertia at a position along the longitudinal axis A_2 having the annular cross-sectional shape. In this manner, the flexural stiffness of the transmission member 320 at a position having the arced cross-sectional shape is substantially less than the flexural stiffness of the transmission member 320 at a position having the annular cross-sectional shape. Furthermore, because the walls 321 have a substantially uniform thickness t , the flexibility of at least a portion of the transmission member 320 can be increased while substantially limiting the loss of stiffness in the axial direction.

The lower area moment of inertia of transmission member 320 at a portion of the transmission member 320 having the arced cross-sectional shape allows the portion to elastically deform more than a portion of the transmission member 320 having a greater area moment of inertia (e.g., having the annular cross-sectional shape). More specifically, the portion having the arced cross-sectional shape can bend (e.g., elastically) about an axis that is perpendicular to the longitudinal axis A_2 of the transmission member 320 without kinking, breaking, or otherwise plastically deforming.

The lower flexural stiffness of the transmission member 320 can allow at least the portion of the transmission member 320 having the arced cross-sectional shape to elastically deform a desired amount while being passed through a tortu-

ous anatomical structure (e.g., a urinary tract, vein or artery), thereby reducing patient discomfort. Moreover, the portions of the transmission member 320 with the arced cross-sectional shape can retain a sufficient stiffness in the axial direction to substantially limit losses of ultrasonic energy transmitted through the transmission member 320 that would otherwise be lost due to forming the transmission member 320 from a material having a lower stiffness. In addition, the transmission member 320 can be configured such that the opening 326 is disposed at a suitable distance from a distal end of the transmission member 320. Thus, the outer diameter d_o of the transmission member 320 can be sufficiently large such that a distal tip of transmission member 320 can deliver ultrasonic energy to a target tissue.

Although not shown in FIGS. 4-6, in some embodiments, a transmission member can be at least partially disposed within an outer member of a probe assembly. For example, in some embodiments, a probe assembly can include an outer member configured to substantially circumscribe the transmission member. In such embodiments, the outer member can be, for example, a catheter or sheath fixedly coupled to the transmission member via an adhesive. In this manner, the outer member can be configured to retain the transmission member within a set of walls (e.g., within a lumen defined by the set of walls) in the event of breakage, thereby limiting the risk of a portion of the transmission member being lost within a portion of the patient.

For example, FIGS. 7 and 8 are schematic illustrations of a probe assembly 410, according to an embodiment. The probe assembly 410 includes a transmission member 420 and an outer member 440. The probe assembly 410 can be included in any suitable ultrasonic energy system such as, for example, the system 100 described above with reference to FIGS. 1 and 2. The transmission member 420 includes a side wall 421 and defines a lumen 422 along a longitudinal axis A_3 . In this manner, the transmission member 420 can provide aspiration from and/or irrigation (via the lumen 422) to a target tissue site during an ultrasonic procedure, as further described below.

The transmission member 420 includes a first portion 423 and a second portion 424. The first portion 423 can be, for example, a proximal end portion, and can be at least operably coupled to an ultrasonic energy source 480, such as for example, the ultrasonic generator 180 and/or the transducer assembly 150 described above. For example, in some embodiments, the first portion 423 can be disposed within a lumen of a coupler member (not shown), as described above with reference to FIG. 2. In such embodiments, the coupler member can be coupled to the ultrasonic energy source 480, thus, operably coupling the transmission member 420 to the ultrasonic energy source 480. The second portion 424 can be, for example, a distal end portion of the transmission member 420, and can be disposed within a body (not shown) to transfer ultrasonic energy from the first end portion 423 into a bodily tissue.

The transmission member 420 defines an elongate opening 426 (e.g., a notch, a groove, a channel, a cutout, etc.) along at least a portion of the longitudinal axis A_3 that is in fluid communication with the lumen 422. The opening 426 can be any suitable shape, size, or configuration. The transmission member 420 can be substantially similar to the transmission member 320 described above with reference to FIGS. 4-6. Therefore, the transmission member 420 is not described in further detail herein.

The outer member 440 includes a proximal end portion 441 and a distal end portion 442 and defines a lumen 443 therethrough. The proximal end portion 441 can be configured to

be disposed adjacent a coupler member. The distal end portion 442 can be disposed adjacent a distal tip of the transmission member 420. More specifically, the distal end portion 442 can be disposed a desired distance from the distal tip of the transmission member 420 such that the outer member 440 does not substantially dampen and/or otherwise interfere with the vibration and/or movement of the distal tip of the transmission member 420 and/or the transmission of the ultrasonic energy therethrough. In some embodiments, the outer member 440 is disposed from the distal end tip by approximately 0.050 to 0.150 inches.

The outer member 440 is coupled to the transmission member 420 such that a portion of the outer member 440 is disposed about the elongate opening 426. In this manner, the lumen 422 is maintained in fluid isolation from a region outside of the transmission member 420. Thus, the lumen 422 can be used to aspirate and/or irrigate a target tissue site disposed adjacent the distal tip of the transmission member 420 during an ultrasonic procedure. More specifically, the ultrasonic energy source 480 can supply ultrasonic energy through the transmission member 420 to a target tissue and the ultrasonic energy source 480 (or other device) can be configured to simultaneously aspirate and/or irrigate the target tissue site via the lumen 422. In addition to maintaining fluid isolation of the lumen 422, the outer member 440 also circumscribes the transmission member 420 to maintain any portions thereof that may result in the event of a failure. Similarly stated, in some embodiments, the outer member 440 can be fixedly coupled to the transmission member 420 such that if a portion of the transmission member 420 breaks, it will be retained within the outer member 440.

In some embodiments, the outer member 440 is fixedly coupled to the transmission member 420. For example, in some embodiments, the outer member 440 can be fixedly coupled to the transmission member 420 via an adhesive, a friction fit, a threaded coupling, or any other suitable coupling method. The outer member 440 can be any suitable member configured to substantially circumscribe the transmission member 420. For example, in some embodiments, the outer member 440 can be a catheter. In other embodiments, the outer member 440 can be formed from multiple layers of material having any given properties. For example, in some embodiments, the outer member 440 can be formed with an outer layer that can be polytetrafluoroethylene (PTFE). In other embodiments, the outer layer can include a hydrophobic coating or a hydrophilic coating. In some embodiments, the outer member 440 can include an inner layer configured to enhance the adhesion properties of the outer member 440 to facilitate the coupling of the outer member 440 to the transmission member 420. Moreover, the arrangement of the outer member 440 is such that the outer member 440 does not limit the desired flexibility of the transmission member 420 disposed therein. Similarly stated, the outer member 420 can be sufficiently flexible to allow the transmission member 420 to deflect within a bodily lumen, as described above.

While the transmission member 420 is shown in FIG. 7 as having an opening that is substantially symmetrical about a plane perpendicular to the longitudinal axis A_3 , in some embodiments, a transmission member can include an opening that is substantially asymmetrical. For example, FIG. 9 is an illustration of a probe assembly 510, according to an embodiment. The probe assembly 510 includes a transmission member 520, defining an elongate opening 526, and an outer member 540. The transmission member 520 and the outer member 540 can be substantially similar in form and function to the transmission member 420 and the outer member 440, respectively, described with reference to FIGS. 7 and 8. Thus,

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the transmission member **520** and the outer member **540** are not described in further detail herein. The transmission member **520** differs from the transmission member **420**, however, in the arrangement of the opening **526**. As shown in FIG. **9**, the opening **526** is configured to be substantially asymmetric about a plane parallel to a longitudinal axis A_4 of the transmission member **520**. In this manner, the flexural stiffness of the transmission member **520** can be further varied along a length of the opening **526** according to the cross-sectional shape of the transmission member **520** at a given position. More specifically, by defining an asymmetrical opening **526**, the cross-sectional shape of the transmission member **520** can be selectively varied along the length of the opening **526**. Furthermore, because the area moment of inertia is dependent on the cross-sectional shape, the area moment of inertia is also selectively varied along the length of the opening **526**.

While the probe assembly **510** is shown in FIG. **9** as having a transmission member **520** defining a single opening **526**, in some embodiments, a transmission member can include any number of openings. For example, FIG. **10** is an illustration of a probe assembly **610**, according to an embodiment. The probe assembly **610** includes a transmission member **620**, defining a first opening **626** and a second opening **628**, and an outer member **640**. Portions of the transmission member **620** and the outer member **640** can be substantially similar in form and function to portions of the transmission member **520** and the outer member **540**, respectively, described above with reference to FIG. **9**. Thus, the portions of transmission member **620** and the outer member **640** are not described in further detail herein.

The transmission member **620** differs from the transmission member **420** and the transmission member **520**, however, by including the first opening **626** and the second opening **628**. In some embodiments, the first opening **626** and the second opening **628** can be substantially similar in shape, size, and/or configuration. In other embodiments, the first opening **626** can be, for example, symmetric about a plane perpendicular to a longitudinal axis A_5 of the transmission member **620** while the second opening **628** can be, for example, asymmetric about a plane perpendicular to the longitudinal axis A_5 (or vice versa). The first opening **626** can be arranged at any spatial orientation relative to the second opening **628**. For example, while shown in FIG. **10** and being disposed on opposite sides of the transmission member **620**, in some embodiments, the first opening **626** and the second opening **628** can be disposed adjacent each other on a similar side of the transmission member **620**. In this manner, the first opening **626** and the second opening **628** can be selectively configured to modify the flexural stiffness of the transmission member **620**. Moreover, the arrangement of the first opening **626** and the second opening **628** can be such that the first opening **626** and the second opening **628** can substantially reduce the likelihood of the transmission member **620** kinking during bending.

Referring now to FIG. **11**, a flowchart illustrates a method **790** for transferring ultrasonic energy to a target tissue within a body of a patient, according to an embodiment. In some embodiments, the method **790** includes inserting at least a distal end portion of a monolithically-constructed transmission member into a bodily lumen, at **791**. In some embodiments, the transmission member can include a flexible portion disposed between a proximal end portion and a distal end portion that has an area moment of inertia less than an area moment of inertia of the proximal end portion and/or an area moment of inertia of the distal end portion. For example, in some embodiments, the transmission member can be substantially similar to any of the transmission members

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described above (e.g., the transmission member **320** described above with reference to FIGS. **4-6**). In this manner, the transmission member can include an opening (e.g., similar to the transmission member **320**) or multiple openings (e.g., similar to the transmission member **620**) disposed along the transmission member such that the cross-sectional shape of the transmission member is changed (e.g., a cross-sectional area of the transmission member is reduced at a position along the opening), thereby decreasing a flexural stiffness of the transmission member. Moreover, in some embodiments, at least a portion of the transmission member can be disposed within an outer member configured to substantially circumscribe at least a portion of the transmission member (e.g., as described above with reference to FIGS. **7** and **8**).

The method **790** includes transmitting ultrasonic energy from the proximal end portion of the transmission member to the distal end portion of the transmission member, at **792**. For example, in some embodiments, the proximal end portion of the transmission member can be operably coupled to an ultrasonic energy source such that the ultrasonic energy source supplies the ultrasonic energy to the transmission member. Moreover, the distal end portion (e.g., at least a distal tip) of the transmission member can be disposed adjacent a target tissue within the body of the patient. In this manner, the transmission member can transmit at least a portion of the ultrasonic energy to the target tissue.

In some embodiments, the method **790** can optionally include aspirating at least a portion of the target tissue via a lumen defined by the transmission member, at **793**. For example, in some embodiments, the transmission member can define a lumen configured to extend through the proximal end portion and the distal end portion of the transmission member. Furthermore, in embodiments in which the transmission member defines an elongate opening, the outer member disposed about the transmission member can be configured to fluidically isolate the lumen from a volume outside of the outer member. Thus, a negative pressure can be applied to the proximal end portion of the transmission member such that a portion of the target tissue (e.g., a portion of the target tissue that is broken apart by ultrasonic energy) can be aspirated through the lumen defined by the transmission member.

The embodiments and/or components described herein can be packaged independently or any portion of the embodiments can be packaged together as a kit. For example, in some embodiments, a kit can include an ultrasonic transducer assembly (e.g., such as the ultrasonic transducer assembly **150** described above with reference to FIG. **2**) and any suitable number of transmission members (e.g., such as the various embodiments described above with reference to FIGS. **3-11**). The transmission members included in the kit can each define a given flexural stiffness that can be different from the flexural stiffness of the other transmission members included in the kit. For example, in some embodiments, each of the transmission members included in the kit can be substantially similar in size and shape as the other transmission members included in the kit but each transmission member can each define a flexural stiffness that is substantially unique to the specific transmission member. Expanding further, in some embodiments, at least one transmission member in the kit can include an opening along a length of the transmission member that substantially reduces an area moment of inertia of the transmission member along the length of the opening. In this manner, one or more transmission members can define an opening of unique shape, size, or configuration such that each transmission member defines a unique flexural stiffness.

In some embodiments, a kit can include an ultrasonic generator similar to the ultrasonic generator **180** shown and

described above. The ultrasonic generator can be configured to distinguish each transmission member contained within the kit, and can automatically adjust the electronic signal produced and/or conveyed to the ultrasonic transducer assembly to correspond to the transmission member coupled thereto. For example, because transmission members defining different levels of flexural stiffness may also have different natural (or resonant) frequencies, in such embodiments, the ultrasonic generator can adjust the frequency of the electronic signal produced to correspond to the natural frequency of the transmission member that is coupled to the ultrasonic transducer assembly.

The processor included in any of the ultrasonic generators can be a general-purpose processor (e.g., a central processing unit (CPU)) or other processor configured to execute one or more instructions stored in the memory. In some embodiments, the processor can alternatively be an application-specific integrated circuit (ASIC) or a field programmable gate array (FPGA). The processor can be configured to execute specific modules and/or sub-modules that can be, for example, hardware modules, software modules stored in the memory and executed in the processor, and/or any combination thereof. The memory included in the ultrasonic generator **180** can be, for example, flash memory, one time programmable memory, a random access memory (RAM), a memory buffer, a hard drive, a read-only memory (ROM), an erasable programmable read-only memory (EPROM), and/or so forth. In some embodiments, the memory includes a set of instructions to cause the processor to execute modules, processes and/or functions used to generate, control, amplify, and/or transfer electric current to another portion of the system, for example, the transducer assembly **150**.

Some embodiments described herein, such as, for example, embodiments related to the ultrasonic generators described above, relate to a computer storage product with a non-transitory computer-readable medium (also can be referred to as a non-transitory processor-readable medium) having instructions or computer code thereon for performing various computer-implemented operations. The computer-readable medium (or processor-readable medium) is non-transitory in the sense that it does not include transitory propagating signals per se (e.g., a propagating electromagnetic wave carrying information on a transmission medium such as space or a cable). The media and computer code (also can be referred to as code) may be those designed and constructed for the specific purpose or purposes. Examples of non-transitory computer-readable media include, but are not limited to: magnetic storage media such as hard disks, floppy disks, and magnetic tape; optical storage media such as Compact Disc/Digital Video Discs (CD/DVDs), Compact Disc-Read Only Memories (CD-ROMs), and holographic devices; magneto-optical storage media such as optical disks; carrier wave signal processing modules; and hardware devices that are specially configured to store and execute program code, such as Application-Specific Integrated Circuits (ASICs), Programmable Logic Devices (PLDs), Read-Only Memory (ROM) and Random-Access Memory (RAM) devices. Other embodiments described herein relate to a computer program product, which can include, for example, the instructions and/or computer code discussed herein.

Examples of computer code include, but are not limited to, micro-code or micro-instructions, machine instructions, such as produced by a compiler, code used to produce a web service, and files containing higher-level instructions that are executed by a computer using an interpreter. For example, embodiments may be implemented using Java, C++, or other programming languages (e.g., object-oriented programming

languages) and development tools. Additional examples of computer code include, but are not limited to, control signals, encrypted code, and compressed code.

The ultrasonic transmission members described herein can be fabricated and/or produced using any suitable methods. In some embodiments a transmission member can be formed via one of more manufacturing process. For example, in some embodiments, a transmission member can be formed via a tube drawing (e.g., drawn through a progressively smaller die (an extrusion process)). In embodiments wherein the transmission member defines an elongate opening (e.g., the transmission member **320** described above), the opening can be formed via water jet cutting, laser cutting, machining (e.g., milling, turning, shearing, etc.). Expanding further, in some embodiments it can be desirable to form an opening along a length of a transmission member via a water jet process because such processes do not produce a heat-affected zone. Thus, the elastic modulus of the material (e.g., stainless steel or the like) that forms the transmission member is not changed. Conversely, in some embodiments it can be desirable to form an opening along a length of a transmission member via a laser cutting process because such processes produce a heat-affected zone. In such embodiments, the heating of the heat-affected zone of the transmission member due to the laser cutting of the opening can have a similar affect as tempering, thus, the stiffness of the material in a region within the heat-affected zone (e.g., along or adjacent to the opening) can be reduced.

Although certain transmission members (e.g., transmission member **320**) are described above as being monolithically constructed, in other embodiments, any of the transmission members described herein can be constructed from two or more separately constructed components that are later joined together.

While the flexural stiffness of transmission members described above is spatially varied by altering the size or shape of the transmission member, in alternate embodiments, manufacturing techniques can be used to spatially vary of the flexural stiffness a transmission member while maintaining a uniform cross-sectional shape. For example, in some embodiments, a portion of a transmission member (e.g., the third portion **222** of the transmission member **220**) can be heat-treated such that the elastic modulus of the portion of the transmission member is changed relative to the elastic modulus of a portion not heat treated. For example, in some embodiments, a portion of a transmission member can be tempered. In other embodiments, a transmission member in its entirety can be variably heat treated. For example, in some embodiments, a first portion can be tempered at a first temperature and a second portion can be tempered at a second temperature, different from the first. In this manner, the flexibility of the first portion and the flexibility of the second portion can be varied according to the temperature of tempering.

The proximal end portion of any of the transmission members described herein can be coupled to the coupler member (e.g., the coupler member **130**) using any suitable mechanism. For example, as shown in FIG. **12**, a probe assembly **810** can include at least a transmission member **820** and a coupler **830**. The transmission member **820** and the coupler **830** can be substantially similar to the transmission member **120** and the coupler **130** described above with reference to FIGS. **1** and **2**, thus, some portions of the transmission member **820** and the coupler **830** are not described in further detail herein. As shown, the coupler **830** includes a proximal end portion **831** and a distal end portion **832** and defines a lumen **833** therethrough. The proximal end portion **831** is configured

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to form a threaded coupling with a transducer horn **863**, as described above in detail with reference to FIG. 2. The lumen **833** has a diameter d_i that can be any suitable size. In this manner, the coupler **830** can be configured to receive (within the lumen **833**) a portion of the transmission member **820**, as described in further detail herein.

The transmission member **820** includes a proximal end portion **821** and a distal end portion (not shown in FIG. 12) and defines a lumen **822** therethrough. The transmission member **820** can be any suitable shape, size, or configuration. For example, in some embodiments, at least a portion of the transmission member **820** is substantially annular and includes an outer diameter d_o and an inner diameter d_i . In some embodiments, the size and shape of the transmission member **820** (e.g., the outer diameter d_o) can substantially correspond to the size and shape (e.g., the diameter d_i) of the lumen **833** defined by the coupler **830** such that the proximal end portion **821** of the transmission member **820** can be disposed therein.

For example, in some embodiments, the diameter d_i of the lumen **833** can be greater than the outer diameter d_o of the transmission member **830**, thus, the transmission member **820** can be disposed within the lumen **833** of the coupler **830**. Furthermore, with the diameter d_i of the lumen **833** greater than the outer diameter d_o of the transmission member **820** an adhesive can be disposed within a void between the transmission member **820** and the inner surface of the coupler **830**. Thus, the transmission member **820** can be fixedly coupled to the coupler **830** without the need for crimping, applying a compressive force to the transmission member or the like. Expanding further, the transmission member **820** can be fixedly coupled to the coupler **830** without plastically (e.g., permanently) deforming the transmission member, thereby decreasing the likelihood of failure and also decreasing losses due to reflections of ultrasonic energy produced by discontinuity. In other embodiments, the transmission member **120** can be coupled via welding or brazing while still realizing the benefits described above.

The transmission members described herein can be any suitable size. For example, in some embodiments, a transmission member (e.g., the transmission member **820**) can have an outer diameter d_o that is approximately 0.032 inches and an inner diameter d_i that is approximately 0.020 inches. In this manner, the transmission member **820** can have a wall thickness of approximately 0.006 inches. In other embodiments, the outer diameter d_o of the transmission member **820** can be between approximately 0.014 to 0.050 inches and the inner diameter d_i can be between approximately 0.010 to 0.040 inches.

While various embodiments have been described above, it should be understood that they have been presented by way of example only, and not limitation. Where methods and/or schematics described above indicate certain events and/or flow patterns occurring in certain order, the ordering of certain events and/or flow patterns may be modified. Additionally certain events may be performed concurrently in parallel processes when possible, as well as performed sequentially. While the embodiments have been particularly shown and described, it will be understood that various changes in form and details may be made.

For example, although the transmission member **320** is shown and described as defining an elongate opening that is substantially linear along the longitudinal axis A_2 , in other embodiments, a transmission member can define an elongate opening that is helical and/or spiraled about the longitudinal axis. In this manner, the area moment of inertia of the region

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of the transmission member that defines the elongated opening can be more uniform about the longitudinal axis.

Although the transducer assembly **150** is shown in FIG. 2 as including two insulators **161** and two piezoelectric rings **162**, in other embodiments, a transducer assembly can include any suitable number of insulators **161** and/or piezoelectric rings **162** in any suitable arrangement. Moreover, the insulators **161** can be formed from any suitable insulating material, ceramic materials (e.g., polyamide, expanded polytetrafluoroethylene (EPTFE), or the like). Similarly, the piezoelectric rings **162** can be any suitable piezoelectric material (e.g., lead zirconate titanate (PZT-5), PZT-8, lead titanate (PT), lead metaniobate (PbNbO₆), polyvinylidene-fluoride (PVDF), or the like).

Although various embodiments have been described as having particular features and/or combinations of components, other embodiments are possible having a combination of any features and/or components from any of embodiments where appropriate. For example, in some embodiments, a transmission member can be a monolithically-constructed member as described with respect to the transmission member **320**, and can also include an outer member coupled thereto, as described above with respect to the transmission member **420**.

What is claimed is:

1. An apparatus, comprising:

a transmission member configured to transfer ultrasonic energy from a first end portion to a second end portion, the transmission member defining a lumen along a longitudinal axis of the transmission member, a sidewall of the transmission member defining an elongated opening therethrough in fluid communication with the lumen; and

an outer member fixedly coupled to the transmission member via an adhesive, a portion of the outer member disposed about the elongated opening such that the lumen is fluidically isolated from a region outside of the outer member.

2. The apparatus of claim 1, wherein a cross-sectional shape of the sidewall defining the elongated opening is an arc.

3. The apparatus of claim 1, wherein a cross-sectional shape of the sidewall defining the elongated opening is an arc having a subtended angle of between approximately 20 degrees and approximately 120 degrees.

4. The apparatus of claim 1, wherein a length of the elongated opening is greater than five times a diameter of the elongated transmission member.

5. The apparatus of claim 1, wherein the elongated opening is one of a plurality of elongated openings defined by the sidewall.

6. The apparatus of claim 1, wherein the transmission member is monolithically constructed.

7. The apparatus of claim 1, further comprising:

a fitting coupled to the first end portion of the transmission member, the fitting configured to couple the transmission member to an ultrasonic energy source.

8. The apparatus of claim 1, wherein an outer diameter of the outer member is constant from a proximal end portion of the outer member to a distal end portion of the outer member.

9. The apparatus of claim 1, wherein:

the transmission member defines a distal end opening, the distal end opening and the lumen collectively defining a flow path, and

the outer member is coupled to the transmission member such that a fluid is conveyed via the transmission member only via the flow path.

10. The apparatus of claim 1, wherein the sidewall defining the elongated opening is disposed in an intermediate portion between the first end portion and the second end portion.

11. The apparatus of claim 10, wherein the intermediate portion defines a cross-sectional area moment of inertia that is less than at least one of a cross-sectional area moment of inertia of the first end portion or a cross-sectional area moment of inertia of the second end portion.

12. The apparatus of claim 10, wherein a cross-sectional shape of the intermediate portion of the transmission member is different than at least one of a cross-sectional shape of the first end portion or a cross-sectional shape of the second end portion.

13. The apparatus of claim 10, wherein the intermediate portion is flexible.

14. The apparatus of claim 1, wherein the elongated opening has a depth of at least half of an outer diameter of the transmission member.

15. The apparatus of claim 1, wherein an outer diameter of the second end portion is the same as an outer diameter of the first end portion.

16. The apparatus of claim 1, wherein an outer diameter of the transmission member is constant.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

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INVENTOR(S) : Shu Du et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In The Specification

Column 19, line 3 "833 has a diameter d_i " should be --833 has a diameter d_j --

Signed and Sealed this
First Day of March, 2016



Michelle K. Lee
Director of the United States Patent and Trademark Office